REMARKS

Claims 1-9 and 11-14 are pending in this application. Claim 13 is amended herein for clarity to more particularly define the invention and is not a narrowing amendment. New claims 15-18 are added herein. Support for this claim amendment and these new claims is found in the language of the original claims and throughout the specification, as set forth below. It is believed that no new matter is added by these amendments. In light of these amendments and the following remarks, applicants respectfully request reconsideration of the application, entry of these amendments and allowance of the pending claims to issue.

I. Rejection under 35 U.S.C. § 103

Claims 1-9 and 11-14 are rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Montagnier et al., in view of Backus et al and Research Genetics. Specifically, the Office Action states that Montagnier et al. discloses primers for detecting HIV-1 and methods of doing same and also teaches explicitly of directing primers to conservative regions and that one such region of conserved sequences is found in the long terminal repeat, or LTR. The Office Action contends that on the basis of these teachings, the Montagnier et al. reference is directing the public to the LTR region for the selection of primers and probes and that this reference provides motivation in selecting sequences that allow for detection of multiple isolates when they teach that the LTR is "highly conserved."

The Office Action also states that Montagnier et al. discloses that by using PCR, which they considered to be more sensitive, one would be able to eliminate viral-isolation assays, but that while Montagnier et al. do teach conducting PCR on the LTR region of HIV, they do not explicitly teach applicants' sequences.

The Office Action goes on to describe Backus et al. as disclosing that primers can range in size or length from 12 to 60 nucleotides and that a preferable range is from 16 to 40 nucleotides and that a more preferable range is from 18 to 35 nucleotides. The Office Action then notes that applicants' SEQ ID NO:1 comprises 18 nucleotides, SEQ ID NO:2 comprises 20 nucleotides, SEQ ID NOs 4 and 5 comprise 20 nucleotides each and SEQ ID NO:12 comprises 30 nucleotides. The Office Action further states that oligonucleotides corresponding to SEQ ID NOs 2, 4 and 24 in the Backus et al. patent comprise the nucleotide sequence as found in applicants' oligonucleotides represented by SEQ ID NOs 1, 2, 4 and 5.

It is further stated in the Office Action that an advertisement in Research Genetics discloses for sale a software program that allows the ordinary artisan to set parameters whereby the software will automatically screen all possible sequence comparisons and provide a listing of those primers that meet the established criteria. The Office Action goes on to state that such parameters to be employed in the selection of primer and probe sequences include desired specificity, length, GC content, secondary structure consideration, etc.

From these alleged disclosures, the Office Action contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the software of Research Genetics with the teachings of Backus et al. and Montagnier et al. to select primers and probes from the LTR region of HIV-1 where such sequences are identified through the use of the commercially available software. The Office Action further states that Backus et al. discloses not only the sequences but directs the public to preferred sizes of primers and that it is noted that the sizes of the primers disclosed by Backus et al. correspond to that claimed in the present application. Thus, the Examiner concludes that with the public being armed with the

sequences, the preferred size ranges and software that will perform necessary calculations and produce nucleotide sequences that meet such criteria, the selection of primer sequences that have such features would have been profoundly obvious. The Office Action continues on with the statement that given the art-recognized sensitivity of PCR and the interest that abounds in HIV diagnostics, the ordinary artisan would have been highly motivated as well and additionally that the ordinary artisan would have been motivated to have configured the primer pair(s) in a kit format as such would be an obvious commercial expedience.

The Office Action then acknowledges applicants' arguments regarding the teachings of Backus et al. of amplification with two sets of primers and concludes that the arguments are not persuasive because claims 1-4, 8 and 9 are drawn to a product and not a method and that therefore, applicants are arguing limitations not found in the claims. The Office Action goes on to state that in so far as methods of amplification are claimed, it is noted that the method claims do not exclude the use of additional primer pairs, which position is supported in part on the use of the term "comprising" which allows for the inclusion of additional method steps and reagents. The Office Action then states that the method claims are considered to encompass the use of single primer pairs as well as an unlimited number of primer pairs and that even if the claims were limited to the use of a single primer pair, it is noted that Backus et al. teaches the use of single sets of primers in performing amplifications.

Applicants respectfully traverse this rejection and maintain their previously asserted position that the claimed invention would not have been obvious to one of ordinary skill in the art at the time this invention was made. In particular, applicants point out that the Examiner has consistently cited the advertisement by Research Genetics in combination with McDonough et al. (July 20, 2000 Office Action), Montagnier et al. (February 14, 2001 Office Action and July 31, 2001 Office Action),

and Montagnier et al. and Backus et al. (April 5, 2002 Office Action and December 18, 2002) in support of his rejection of all the claims under 35 U.S.C. § 103. Thus, this reference has been included in an obviousness rejection of the pending claims five times now in combination with various other art references, indicating to applicants that although the other art references have varied, it is the Examiner's position that this advertisement in particular is essential in supporting a rejection of the pending claims as obvious. Applicants have reviewed this advertisement and presented detailed arguments to the Examiner in both the December 19, 2000 response and the June 13, 2001 response, setting forth several well-reasoned statements regarding why the use of the software program described in the advertisement by Research Genetics would not produce the oligonucleotides and/or primer pairs of the claimed invention without knowledge of the present invention and with or without the teachings of McDonough et al, Backus et al. and/or Montagnier et al., thus leading to the reasonable conclusion that this reference does not render the claimed invention obvious. Applicants have requested a detailed response to these arguments from the Examiner and have even requested that the Examiner "...make of record appropriate evidence indicating all the capabilities of the prior art that is being cited." (page 3, third paragraph of June 13, 2001 response.)

However, although the Office Action states that applicants' arguments have been considered and have not been found persuasive in overcoming this rejection, applicants have never received a detailed explanation regarding why the arguments presented by applicants fail to demonstrate why the use of the Research Genetics software program does not render the claimed invention obvious. Instead, the same brief paragraph of what is disclosed in the advertisement appears again and again in each subsequent Office Action and there has been no further comment from the Examiner regarding this particular reference or any specific reply to applicants' comments about this reference. Thus, applicants reiterate all of the arguments

previously of record in this case and now specifically request a more detailed explanation from the Examiner regarding why these arguments fail to overcome the present rejection, with comment particularly requested in response to applicants' arguments regarding the Research Genetics advertisement.

Applicants also point out that although new claims 13 and 14 were added in the September 5, 2002 response, these new claims have been lumped together with the previously pending claims and all of the claims are rejected together in the present Office Action for the same reasons provided in previous Office Actions, without any comment on these new claims in particular.

Applicants wish to point out that the oligonucleotides of claims 13 and 14 consist of specific nucleotide sequences and specific pairs of said specific nucleotide sequences and neither these specific sequences nor these specific pairs of specific sequences are taught or suggested in the cited art. It is applicants' position that the subject matter of all of the claims and in particular, the subject matter of claims 13 and 14 is neither anticipated nor rendered obvious by the teachings of the cited art and that this rejection should be withdrawn. However, if the Examiner continues to maintain the current rejection of all of the claims, applicants specifically request a detailed explanation of why the subject matter of claims 13 and 14 in particular would have been obvious to one skilled in the art at the time this invention was made.

As set forth above and for the reasons previously made of record, applicants believe the pending rejection under 35 U.S.C. § 103 is overcome, absent convincing evidence to the contrary. Thus, applicants respectfully request the withdrawal of this rejection and the allowance of the pending claims to issue.

II. Amendment of claim 13 and addition of new claims 15-18

Claim 13 is amended herein to add the nucleotide sequence of SEQ ID NO:9 to the nucleotide sequences that make up the group of first hybridizing oligonucleotides. Support for this amendment is found, for example, in currently pending claim 4 and throughout the specification. New claims 15 and 16 depend from previously pending claim 13 and provide a specific first hybridizing oligonucleotide and a specific second hybridizing oligonucleotide as set forth in the groupings of claim 13. New claims 17 and 18 are identical to pending claim 14, with the exception that they depend from new claims 15 and 16, respectively. Thus, support for these new claims is found in the language of previously pending claims and no new matter is added by this amendment or these new claims.

Applicants also wish to point out that the specific oligonucleotides set forth in claim 13 as amended herein and in new claims 15-18 are free of any art rejections applied to any previously pending claims. Specifically, the subject matter of these new claims and of claim 13 as amended is neither anticipated nor rendered obvious by any of the cited art and applicants respectfully request their allowance. If however, the Examiner takes the position that these claims are obvious in view of the same art cited against the previously pending claims, then applicants request that a detailed explanation be provided regarding why these claims in particular are rejected, rather than receiving another blanket rejection of all the claims without itemization.

The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue.

A check in the amount of $430.00 ($110.00 extension fee and $320.00 Notice of Appeal fee) is enclosed. This amount is believed to be correct. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account 50-0220.

Respectfully submitted,

Mary L. Miller
Registration No. 39,303

20792
PATENT TRADEMARK OFFICE

CERTIFICATE OF EXPRESS MAILING

"Express Mail" mailing label number: EV 193628080 US Date of Deposit: April 10, 2003
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Box AF, Commissioner for Patents, Washington, DC 20231.

Monica L. Croom

APPENDIX

MARKED UP VERSION SHOWING CHANGES MADE

Please amend the claims as follows:

13. (amended) A pair of oligonucleotide primers consisting of:

(i) a first hybridizing oligonucleotide selected from the group consisting of:

SEQ ID 1: G GGC GCC ACT GCT AGA GA;

SEQ ID 2: G TTC GGG CGC CAC TGC TAG A; [and]

SEQ ID 3: CGG GCG CCA CTG CTA; and

SEQ ID 9: aat tct aat acg act cac tat agg gAG AGG GGC GCC ACT GCT AGA GA; and

(ii) a second hybridizing oligonucleotide selected from the group consisting of:

SEQ ID 4: CTG CTT AAA GCC TCA ATA AA;

SEQ ID 5: CTC AAT AAA GCT TGC CTT GA; and

SEQ ID 12: GAT GCA TGC TCA ATA AAG CTT GCC TGG AGT.